IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Kim McClure et al.	Examiner:	Jon P. Weber
Serial No:	09/373,182	Art Unit:	1651
Filed:	August 12, 1999	Docket:	17088 (PC 10240A)
For:	TACE INHIBITORS	Dated:	January 26, 2004

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR RECONSIDERATION

Sir:

In response to the final rejection dated July 25, 2003, reconsideration of the above-identified application and allowance is hereby requested.

In the Final Office Action, claims 61, 81-83 stand rejected under 35 U.S.C. §112, first and second paragraph. This rejection is respectfully traversed.

The present invention is directed to a method of inhibiting cleavage of TNF-α without inhibiting MMP-1. The method comprises administering a selective hydroxamic acid which possesses an in vitro IC_{50} selectivity for TACE over MMP-1 of at least 100-500 fold.

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, Alexandria VA 22313-1450, on January 26, 2004.

Dated: January 26, 2004

Peter I. Bernstein

According to the Examiner, as set forth in the Final Office Action, the claims were rejected under 35 U.S.C. §112, second paragraph, as allegedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner stated it was unclear what the overall structural relationship is between the substituents and the hydroxamate compound.

Applicants have amended the claims, which when considered with the comments hereinbelow are deemed to place the present case in condition for allowance. Favorable action is requested.

Applicant has amended pending claims 61, 81-83 to explicitly recite the structural relationship between the substituents and the hydroxamate compound. The structure of the hydroxamic acid compound has been provided for clarification and to place the application in condition for allowance. No new matter has been added to the application. Thus, the rejection of claims 61, 81-83 under 35 U.S.C. §112, second paragraph, is obviated. Withdrawal thereof is respectfully requested.

Each of the pending claims was also rejected under 35 U.S.C. §112, first paragraph as lacking enablement. The Examiner alleges that the specification, while being enabling for specific compounds that are selective for TACE over MMP1, does not reasonably provide enablement for any hydroxamate compounds.

Although required for a §112, first paragraph rejection, the Examiner has not stated specific technical reasons why one would not expect to be able to extrapolate the examples across the entire scope of claims. No reasons are advanced by the Examiner to establish that a person skilled in the art could not apply the example to the genus of hydroxamic acid compounds as a whole without undue experimentation. No specific

findings of fact, supported by the evidence have been provided. Nor has the Examiner identified what information is missing and why one skilled in the art could not supply the information without undue experimentation. When the U.S. Patent & Trademark Office denies a patent, the Office must set forth at least a *prima facie* case as to why an applicant has not met the statutory requirements of 35 U.S.C. §112, first paragraph. This has not been done in this case.

The four basic elements in the Federal Circuit test for enablement include: whether the patent disclosure enables 1) one skilled in the art, 2) at the time the patent application was filed, 3) to make and use the claimed invention, 4) without undue experimentation. As the Examiner himself has stated, the decisive element of the test is "without undue experimentation."

With regard to the Examiner's statement that the specification, while being enabling for specific compounds that are selective for TACE over MMP1, does not reasonably provide enablement for any hydroxamate compounds, applicants have provided a formula genus of hydroxamic acids and various specific embodiments in the amended claims. Applicants maintain that the patent disclosure contains the novel aspect of the invention. Applicants have also provided clear direction on the type of assays to be used to identify the compounds: for TNF- α selectivity, human monocyte assay; for MMP-1, *in vitro*. Applicants also supplied a list of publications employing the techniques employed in the specification to determine the selectivity questioned by the Examiner.

Paragraph 1 of 35 U.S.C. §112 permits resort to material outside of the specification in order to satisfy the enablement portion of the statute because it makes no

sense to encumber the specification of a patent with all the knowledge of the past concerning how to make and use the claimed invention. It is not necessary to supply information already known or available to those of skill in the art. *See Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co., 221 U.S.P.Q. 481, 489 (Fed. Cir. 1984).*

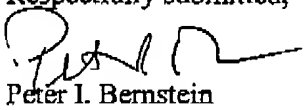
The Examiner has stated that one skilled in the art can not make and use the claimed invention without undue experimentation. Applying the *Wands* factors, the Examiner has not specified what quantity of experimentation is necessary; what further amount of direction or guidance should be presented; or what types of further examples are necessary. The Examiner has not met the burden of giving reasons, supported by the record, why the specification is not enabling. *See In re Angstadt, 190 U.S.P.Q. 214, 219 (C.C.P.A. 1976).* Moreover, every specific embodiment is not required. Additionally, following the Examiner's approach would require a patent specification to be a blueprint which, if followed, would unfailingly reproduce exactly the applicant's claimed invention. However, the law does not require a specification to be a blueprint in order to satisfy the requirement for enablement under 35 U.S.C. §112, first paragraph. *See Stataehelin v. Secher, 24 U.S.P.Q. 2d 1513, 1516 (B.P.A.I. 1992).* Nor is it required that a patent must disclose information sufficient to manufacture a commercial product incorporating the invention. *See Christainson v. Colt Indust. Operating Corp., 3 U.S.P.Q. 2d 1016, 1027 (Fed. Cir. 1987), vacated on other grounds, 486 U.S. 800 (1988).*

The present claims are method of use claims, the scope of which are not broader than the teaching in the specification. Applicants maintain that the specification is commensurately enabling relative to the scope of the amended claims and it would not

take undue experimentation for one of ordinary skill in the art to produce embodiments falling within the scope of the claims beyond any embodiment adequately disclosed in the specification. When claiming in terms of use, "the law requires that the disclosure in the application shall inform [those skilled in the art] how to use, which applicants maintain the present specification does." *See In re Garner, 427 F.2d 786 at 789, 166 U.S.P.Q. 138 at 141 (C.C.P.A. 1970).*

It is, therefore, respectfully requested that the rejection under 35 U.S.C. §112, first and second paragraphs be reconsidered and withdrawn and a favorable action is hereby solicited.

Respectfully submitted,



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